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REMARKS

After entry of the foregoing amendments, Claims 1-5, 9, 11-15, 22-23, 31-35, 38-39, 42, and 69-75 are presented for examination. By the foregoing amendments, Claims 6-8, 40-41, 44-52, and 67-68 are cancelled without prejudice. New Claims 71-75 have been added as set forth above. Claims 1, 13, 14, 22-23, 31-33, 35, 38-39 and 70 have been amended as set forth above. The new claims and the amended claims are supported by the specification and the claims as originally filed. Therefore, no new matter has been added. The specific changes to the amended claims are shown above with the insertions being underlined and the ~~deletions shown stricken through~~.

Statement of the General Substance of October 7, 2003 Telephone Interview

Applicants' representatives, Richard Campbell and Marc Morley thank Examiner Shapiro for the telephone interview conducted on October 7, 2003. The substance of the interview included discussion of the claims and possible directions for future amendments, and discussion focusing on the sampling system and its interface with the rest of the system.

Rejections Under 35 U.S.C. § 103(a)

In the Office Action Claims 1-15, 22-23, 31-35, 38-42, 44-52 and 67-70 were rejected under 35 U.S.C. § 103(a) as being anticipated by Liff et al. ("Liff") (U.S. Patent No. 6,068,156).

To establish a *prima facie* case of obviousness a three-prong test must be met. First, there must be some suggestion or motivation, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success found in the prior art. Third, the prior art must reference must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

Respectfully, the pending claims are not obvious in view of Liff for the reasons set forth below. In general, Liff is directed to a prescription drug dispensing system and methods for filling patient prescriptions. However, Liff does not teach or suggest each and every element of amended independent Claims 1, 22, 31, and 35.

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Claim 1

Claim 1 as amended includes, *inter alia*, a marketing subsystem, a sample management subsystem and a prescription subsystem. A *prima facie* obviousness case requires that the cited reference teach or suggest all of the claim limitations.

Liff Does Not Teach or Suggest a Marketing Subsystem

Liff is the only reference relied upon in the Office Action. Liff fails to teach any sort of marketing. In fact, a search of Liff shows that the words “market” or “marketing” do not appear anywhere in the text of the reference. Claim 1 requires a marketing subsystem that, *inter alia*, is configured to gather data regarding the distribution of sample medications, to transmit the data, and to receive, in response to the transmission of the data, marketing information for an individual dispensing the sample medication. Liff does not describe any such system, including for example, one configured to receive in response to the transmission of medication distribution data, marketing information for an individual dispensing the medication. Liff provides no suggestion or teaching that any sort of marketing information is received in response to the transmission of data regarding medication usage.

The Office Action attempts to find a suggestion for the marketing subsystem of Claim 1 based upon the ordinary skill in the art, but there is no support in the record for such a suggestion. Nonetheless, the Office Action concludes that the marketing subsystem is obvious in view of Liff because the Liff system “stores such information as patient records and that it would, at the very least, be expedient for one of ordinary skill in the art to use and manipulate such data to determine sales and marketing objectives.” Respectfully, Applicants disagree that Liff, the only reference cited, provides any suggestion of a marketing subsystem. There is no evidence in Liff that the listed information could be used for marketing, no suggestion to use the information for sales objectives, and no evidence in the record showing that one of ordinary skill in the art would find such a suggestion.

Therefore, Liff does not teach any sort of marketing, including a marketing subsystem. Further, there is no support for the proposition that Liff suggests marketing beyond unsupported conclusions in the Office Action.

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Liff Does Not Teach or Suggest a Sample Management Subsystem

Claim 1 requires a sample management subsystem. Liff does not teach sample management. Again, Liff is the only cited reference. Nowhere in Liff are sample medications discussed or described.

Liff does not even suggest a sample management subsystem. The Office Action concludes that distribution of trial drugs as part of a clinical trial is the functional equivalent of sample distribution. Applicants disagree with this conclusion. Sample medication distribution is not the functional equivalent of the distribution of a trial drug as part of a clinical trial. There is no suggestion in Liff that a clinical trial distribution system is the equivalent of a sample management system. Liff does not suggest that the clinical system could be used for other types of medications. There is nothing in the record supporting the conclusion that sample management and clinical trial distribution are equivalents in the art.

Furthermore, the clinical drug system of Liff cannot be the equivalent because it is different from the claimed sample management subsystem in a number of ways. For example, there is no teaching or suggestion, that the Liff clinical system is configured to initiate a determination of whether the medication is appropriate for a patient. Also, Liff does not teach or suggest marketing associated with clinical trials and clinical trial drugs. Clinical drugs are not yet approved for marketing, whereas samples are generally already approved medications that can be distributed. Further, Liff does not teach or suggest gathering data regarding clinical trials for use in marketing. Liff is the only cited reference and there is nothing else on the record teaching sample management or suggesting that a clinical trial is the functional equivalent of sample management.

In summary, Liff does not teach or suggest a sample management subsystem and there is no other evidence of record providing the teaching or suggestion. Furthermore, the claimed sample management subsystem is not the functional equivalent of a clinical trial management system. Liff provides no suggestion for such a conclusion, and likewise, there is no other support on the record.

Liff Does Not Teach or Suggest Marketing in Connection with Sample Management

As discussed above, Liff does not teach or suggest marketing. Likewise, Liff does not teach or suggest sample management. Not surprisingly, Liff also does not teach marketing in

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connection with sample management, and there is nothing else on the record that teaches or suggests marketing or sample management, alone or combined.

Thus, Liff does not teach or suggest the claimed marketing subsystem in communication with a clinical trial system, much less one that is in communication with a sample management subsystem. Also, Liff does not teach a marketing subsystem configured to gather data regarding the distribution of a clinical drug, and therefore, also does not teach gathering data regarding sample distribution as set forth in Claim 1. In addition, Liff does not teach a marketing system configured to transmit clinical drug distribution data. Furthermore, Liff does not teach a marketing system configured to receive, in response to the transmission of clinical drug distribution data, marketing information for the individual distributing a clinical drug. Therefore, Liff does not teach or suggest marketing in connection with clinical drug distribution or in connection with sample distribution. There is no other teaching or suggestion on the record to support such a combination.

Liff is the only cited reference. Liff does not teach or suggests all of the limitations of Claim 1. Nothing else in the record teaches or suggest all of the limitations of Claim 1. Liff does not teach or suggest, for example, a marketing subsystem, a sample management subsystem, or a prescription subsystem, alone or in any combination. Therefore, amended Claim 1 and its dependent claims are not obvious in view of Liff.

Claim 22

Liff does not teach, suggest, each and every element of amended Claim 22. Claim 22 as amended is directed to a sample medication dispenser.

As already discussed above, Liff does not teach or suggest a system that manages sample medications. Despite the conclusions in the Office Action, there is no teaching or suggestion in Liff that clinical trial drug distribution is the functional equivalent of sample management. Furthermore, nothing on the record supports that conclusion.

Also, clinical trials and the clinical trial distribution system described in Liff are different from the claimed sample medication dispenser. For example, clinical trials are limited to the distribution of only one drug, and in some cases perhaps a non-drug placebo. It follows that Liff does not teach or suggest a clinical drug dispensing system that distributes one of three or more

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clinical medications or sample medications. Similarly, Liff does not teach a clinical trial system that receives "a request to distribute a clinical or sample medication selected from the three or more sample medications." Also, Liff does not initiate a determination of whether the clinical trial drug is appropriate for a patient. Further, Liff does not teach a clinical trial system that receives a request to distribute one of three or more clinical trial drugs. The clinical trial system of Liff is different from the claimed sample medication dispenser.

Thus, the cited art of record does not teach or suggest all of the limitations of amended Claim 22. Therefore, amended Claim 22 and its dependent claims are not obvious in view of Liff.

Claim 31

Claim 31 as amended includes, *inter alia*, a sample management module and a marketing module. Liff does not teach or suggest each and every limitation of amended Claim 31. There is nothing else on the record that teaches or suggests each and every limitation of Claim 31.

The sample management module is similar to the sample management subsystem discussed above, and the marketing module is similar to the marketing subsystem discussed above. For reasons similar to those discussed above, Liff, the only cited reference does not disclose a system which includes, alone or in combination, a sample management module and a marketing module.

Again, as discussed in connection with Claim 1, Liff does not disclose sample management or marketing alone. Also, Liff certainly does not teach or suggest the claimed combination that includes, *inter alia*, a sample management module and a marketing module.

Therefore, Liff does not obviate amended Claim 31 or any claims depending therefrom.

Claim 35

Liff does not teach or suggest each and every element of amended Claim 35. Claim 35, as amended is directed to a system that includes, *inter alia*, a sample management module and an inventory management module.

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Liff Does Not Teach or Suggest Sample Management

The sample management module of Claim 35 is similar to the sample management subsystem discussed above. For reasons similar to those set forth above, Liff does not teach or suggest the sample management module of Claim 35.

Liff Does Not Teach or Suggest Virtual Inventory Management

Liff is the lone cited art relied upon and it does not teach virtual inventory management. There is no suggestion in Liff of virtual inventory management. The Office Action concludes the virtual inventories and actual inventories are functionally equivalent. Respectfully, Applicants disagree. Liff does not suggest such equivalence and there is no other evidence on the record doing so. Actual inventory management or physical inventory management is different from virtual inventory management. For example, the claimed virtual inventory management tracks ownership and dispensing of individually owned medications that are co-mingled or stored in the same location, for example the same dispenser. Liff provides no teaching or suggestion of such inventory management.

Liff Does Not Teach or Inventory Management of Sample Medications

Liff does not teach an inventory management module configured to control and manage the physical and the virtual inventory of sample medications. As mentioned above, the Office Action equated sample medication management with clinical trial drug distribution. The clinical trial drug distribution system of Liff is not described as including inventory control, and especially not a virtual inventory control. Liff also does not suggest inventory management for clinical trials. Furthermore, Liff does not teach or suggest a system which tracks ownership and dispensing of a plurality of individually owned and co-mingled medication inventories. Clinical trials administering a single drug do not involve co-mingled inventories with different ownership entities. Thus, Liff does not teach inventory management of sample medications. There is no other evidence of record providing such teaching or suggestion.

Therefore, Claim 35 is not obvious in view of because Liff does not teach or suggest each and every element of Claim 35.

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CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the cosmetics of the claims. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of the pending claims, the same is invited to contact the undersigned.

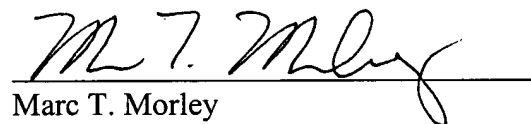
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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